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South African
Health Products
Regulatory Authority

Update on Interferon alpha2b

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17 February 2021

Section 21 as per the Medicines Act

- SAHPRA may, in certain circumstances, and in accordance with Section 21 of the Act, authorise the sale of an **unregistered medicine** for such **purposes** and in **such manner** and during such **period** as the Authority may determine.
- Regulation 29 of the General Medicines Regulations applies to Section 21 authorisations.
- A Section 21 authorisation is to provide access to unregistered medicines on an exceptional basis, where conventional therapies have been ruled out, have failed or are unavailable as marketed products. It is also use when clinical trial enrollment is not a possibility.
- This must always have regard to the safety, efficacy and quality of medicines accessed through Section 21 which are set out in Regulation 29.

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Background on INF alpha2b

- INF alpha 2b is an antiviral /antineoplastic drug
  - Used for the treatment of hairy cell leukemia, malignant melanoma, Kaposi's sarcoma caused by AIDS etc
- Registered in SA for the above conditions
- NEMLC review of 24th November 2020
  - Not recommended for use in treatment of of COVID-19 hospitalized patients, but could be considered under clinical trial
- WHO also did not recommend its use outside of a clinical trial.
  - Included in the Solidarity trial for COVID-19 treatments
  - Had little or no effect on hospitalized COVID-19 patients in terms of overall mortality, initiation of ventilation and duration of hospital stay

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What approvals were granted/not granted?

- 27 August 2020 – SAHPRA received a new application for bulk stock of Heberon (Recombinant Human Interferon alpha-2b), no quantities were mentioned, no further was information supplied on clinical benefit, the application was **rejected**.
- 05 October 2020 – SAHPRA received a named-patient authorisation request " to boost defence against COVID-19 complications" for the use of 10 vials of Heberon (Recombinant Human Interferon alpha-2b), the application was **approved**. This is detailed in the next slide.
- 21 October 2020 – SAHPRA received a bulk stock authorisation request for Heberon (Recombinant Human Interferon alpha-2b), no quantities were mentioned, no further information was supplied and the application was **rejected** with recommendation that all relevant details about the application be submitted to SAHPRA through section21@sahpra.org.za.
- There has been no further supporting details submitted to SAHPRA till date.

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Inspection of facility

- SAHPRA became aware of the matter of the product interferon alpha 2B being in the possession of the South African National Defense Force (SANDF) in November 2020.
  - The product was imported by SANDF without SAHPRA authorization in November 2020
- SAHPRA Inspectors first engaged with L/Col Oma Mohammed (11th November 2020), Pharmacist responsible for SANDF.
  - At this meeting, Mr Mohammed referred SAHPRA inspectors to Col Lorraine May, who is the Officer in Command for Military Health Services.
  - Numerous attempts to reach Col May failed.
- SAHPRA visited the SANDF site, Military Health Base Depot, Pretoria on the 29th January 2021 together with the HAWKS.
  - As the SANDF is not authorized to import the said product, SAHPRA inspectors were accompanied by HAWKS.
  - The general practice at SAHPRA when investigating facilities that are not licensed by SAHPRA is to be accompanied by SAPS or the HAWKS.
  - Col May, availed herself for this visit. Col May requested to postpone the meeting after SAHPRA informed her of the reason for the visit
- SAHPRA Inspectors requested to inspect the consignment and Col May agreed. The medicines were adequately store in Cold Room in the Warehouse
- Meetings to discuss a way forward scheduled for 3rd February 2021 did not proceed

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Agreed way forward

- SAHPRA met SANDF on 9th February 2021 align on the developments
- A follow-up meeting was held between SAHPRA and SANDF on the 12 February 2021
- The parties discussed the proposed way forward on Heberon.
  - It was agreed that SANDF will submit a clinical trial application for the product.
  - SAHPRA will, on receipt of the clinical trial application expedite the review as it has been the case with other COVID-19 clinical trial application
  - A small technical team from both parties will be constituted to look at technical requirements prior to the submission
  - SAHPRA and SANDF will issue on joint press statement

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Thank you